



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0248]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

*REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2012-N-0248 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before

submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

OMB Control Number 0910-0430--Extension

This information collection approval request is for FDA guidance on the process for formally resolving scientific and procedural disputes in FDA's CDER and CBER that cannot be resolved at the division level. The guidance document describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue or issues presented. The guidance document provides information on how the Agency will interpret and apply provisions of the existing regulations regarding internal Agency review of decisions (§ 10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (§ 312.48 (21 CFR 312.48)) and the new drug application/abbreviated new drug application (NDA/ANDA) process (§ 314.103 (21 CFR 314.103)). In addition, the guidance document provides information on how the Agency will

interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the Agency, CDER, and CBER. All Agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in part 312 (OMB control number 0910-0014), part 314 (OMB control number 0910-0001), and part 601 (21 CFR part 601) (OMB control number 0910-0338), which specify the information manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. Although FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of information regarding the request itself and the data and information that the requestor relies on in the appeal would facilitate timely resolution of the dispute. The guidance document describes the following collections of information not expressly specified under existing regulations: the submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations ((§§ 312.23(a)(11) and (d) (21 CFR 312.23(a)(11) and (d)), 314.50 (21 CFR 314.50), 314.94 (21 CFR 314.94), and 601.2 (21 CFR 601.2)) state that information provided to the Agency as part of an IND, NDA, ANDA, or BLA must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs

and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: Form FDA 1571 (OMB control number 0910-0014) and Form FDA 356h (OMB control number 0910-0338).

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the Agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted as an amendment in this manner for two reasons: (1) to ensure that each request is kept in the administrative file with the entire underlying application; and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the appropriate Agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance document recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the center may quickly and efficiently respond to the request: (1) a brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last Agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file or additional copies of such documents that are deemed

necessary for resolution of the issue or issues; and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information the Agency suggests submitting with a formal request for dispute resolution consists of: (1) statements describing the issue from the perspective of the person with a dispute; (2) brief statements describing the history of the matter; and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the Agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance document will be minimal.

Provided in this document is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately 12 sponsors and applicants (respondents) will submit requests for formal dispute resolution to CDER annually and approximately one respondent will submit requests for formal dispute resolution to CBER annually.

The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 17 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with the guidance document, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting



information that has already been submitted to the Agency. Based on experience, FDA estimates that approximately 8 hours, on average, would be needed per response. Therefore, FDA estimates that 8 hours will be spent per year by respondents requesting formal dispute resolution in accordance with the guidance document.

FDA estimates the burden of this collection of information as follows:

Table 1.-- Estimated Annual Reporting Burden<sup>1</sup>

Requests for Formal Dispute Resolution	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
CDER	12	1.42	17	8	136
CBER	1	1	1	8	8
Total					144

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden for this information collection has changed since the last OMB approval.

Our burden estimate reflects a decrease in burden by 14 records and 112 hours. We attribute this adjustment to a decrease in the number of requests received over the last few years.

Dated: August 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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